IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JEREMY OLSEN,

Plaintiff,

v.

ALEX AZAR, in his capacity as Secretary of the United States Department of Health and Human Services,

Defendant.

Case No. 1:19-cv-03814

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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Plaintiff Mr. Jeremy Olsen files this motion for summary judgment. As detailed in the Complaint and below, Mr. Olsen is a Type I diabetic who also suffers from "brittle" diabetes with hypoglycemic unawareness. Mr. Olsen's diabetic condition resulted in damage to his kidneys, leading to kidney failure, and necessitating a kidney transplant. Both to address his underlying diabetes and to protect his transplanted kidney from damage as a result thereof, Mr. Olsen's treating physician prescribed a continuous glucose monitor (CGM). As its name implies, a CGM continuously tests glucose levels, alerts the user of out of range values, and, in Mr. Olsen's case, communicates with an insulin pump (which Mr. Olsen also has) to automatically adjust insulin dosage.

Incredibly, Mr. Olsen's claim for Medicare coverage of his CGM has been rejected by the Secretary on the grounds that a CGM is not "primarily and customarily used to serve a medical purpose."[1] This non-sensical position has already been rejected by three United States District Courts in decisions that have become final. Indeed, in each of those cases, the court found that the Secretary's position lacked "substantial justification" and ordered the Secretary to pay the plaintiffs' attorneys fees for having to litigate the issue.

Beyond being non-sensical, the Secretary's decision is also based on a Ruling issued, and applied to Mr. Olsen, in violation of law. Pursuant to 42 U.S.C. § 1395hh, before the Secretary can issue any rule, requirement, or policy that establishes or changes the rules regarding coverage, the Secretary must comply with the "notice and comment" requirements of the Medicare Act (which are more strict than those under the Administrative Procedure Act). Without complying

[1] This is so even though the Council decision itself states: "Neither CMS in its referral, nor the Council in this decision, questions the appellant's medical condition, the judgment of his doctors, or the utility of the CGM to him." *See* Declaration of Jeffrey Blumenfeld in Support of Plaintiff's Motion for Summary Judgment ("Blumenfeld Declaration"), Exhibit F at 7.

with those requirements, the Secretary issued CMS Ruling 1682-R changing the regulatory requirement by holding that only "therapeutic" CGMs (*i.e.*, those that completely replace the need for finger sticks) would be covered going forward.[2] That Ruling forms the basis for the denial in Mr. Olsen's case. That is a violation of the law. Moreover, even taken at face value, the Ruling is not supported by substantial evidence, is arbitrary and capricious, and/or contrary to law.

Mr. Olsen's CGM qualifies as covered durable medical equipment and the Secretary's decision otherwise should be reversed as arbitrary and capricious, contrary to law, and not supported by substantial evidence. This Court should order the Secretary to cover Mr. Olsen's claim and remand with an Order to effectuate the Court's decision.

I. BACKGROUND

A. Factual Background

Jeremy Olsen is a 41-year old father of three and a journeyman carpenter. In his free time, Mr. Olsen enjoys fixing up old cars, woodworking, and crafts activities. First diagnosed with Type I diabetes at the age of nine (9), Mr. Olsen is a "brittle" diabetic (*i.e.*, his glucose levels are prone to wild and rapid swings). In addition, Mr. Olsen suffers from hypo/hyperglycemic unawareness (*i.e.*, he has no physical sensations – headaches, sweats, etc. – that alert him his glucose levels need to be adjusted). To assist with management of his diabetes, Mr. Olsen was fitted with an insulin pump. Prior to receiving an insulin pump and a CGM, Mr. Olsen had to be revived at the Emergency Room more than 20 times because of his uncontrolled diabetic condition.

As a result of his diabetic condition, Mr. Olsen suffered from kidney failure. In 2016, Mr. Olsen had kidney and pancreas transplant surgery. Although it was hoped that the pancreas

[2] All other CGMs (including the Medtronic MiniMed CGM) would be characterized as "precautionary" and not covered.

transplant would address Mr. Olsen's diabetes, the transplant did not succeed and Mr. Olsen continues to suffer from diabetes.

In 2018, Mr. Olsen was prescribed a Medtronic MiniMed 670G[3] continuous glucose monitor by his treating physician for two reasons. First, of course, given his brittle diabetes and hypo/hyperglycemic unawareness, traditional finger stick checking was not sufficient to manage Mr. Olsen's diabetes such that he continued to suffer a risk of death and other complications. Second, out of range glucose levels as a result of the diabetes jeopardized Mr. Olsen's transplanted kidney.

A CGM consists of three components: 1) a sensor that is placed under the skin; 2) a transmitter that transmits readings from the sensor; and 3) a receiver that receives signals from the transmitter and displays the computed values and/or takes other actions. Using the sensor, CGMs test glucose levels every 5-7 minutes (*i.e.*, nearly 300 times a day) and report the results to the user. While the actual value is important, the trend of the values (going up or down) is likewise important because it lets the user know what action, if any, must be taken. Of course, traditional finger sticks/blood monitors cannot test as frequently or report trend information.

The Medtronic MiniMed CGM also communicates with Mr. Olsen's insulin pump to properly regulate the amount of insulin being dispensed and to alert Mr. Olsen of out of range glucose levels. Since receiving an insulin pump and the CGM which interfaces with it, Mr. Olsen has not had to visit the Emergency Room as a result of his diabetic condition.

On March 14, April 18, and June 5, 2018, Mr. Olsen received supplies related to his CGM including sensors, an external transmitter, and water-proof tape. Mr. Olsen's claim for coverage

[3] As noted in CMS' Referral, the Medtronic MiniMed 670G is an FDA approved, continuous glucose monitor. *See* Blumenfeld Declaration, Exhibit E at 9, n. 5.

for these items was rejected on July 13, 2018 on the grounds that "Medicare does not pay for this item or service." *See* Blumenfeld Declaration, Exhibit A. Thereafter, Mr. Olsen sought redetermination. Mr. Olsen's request for redetermination was denied on October 11, 2018 on the grounds that Mr. Olsen's CGM did not meet the definition of "therapeutic" in CMS 1682-R and, therefore, that coverage was barred. *See* Blumenfeld Declaration, Exhibit B. Thereafter, Mr. Olsen sought reconsideration.

Mr. Olsen's request for reconsideration was denied on December 18, 2018. *See* Blumenfeld Declaration, Exhibit C. Rather than alleged non-compliance with CMS-1682-R, Mr. Olsen's request was denied on the grounds that the file did not contain an order for the items at issue. *Id.* Thereafter, Mr. Olsen filed an appeal that was assigned to ALJ Lambert.

After conducting a hearing in which CMS chose not to participate, on March 14, 2019, ALJ Marc Lambert issued a decision (ALJ Appeal No. 1-8237389961). *See* Blumenfeld Declaration, Exhibit D. There, ALJ Lambert found that:

> Per a physician letter dated February 15, 2017, an insulin pump with a continuous glucose sensor was necessary to preserve the [kidney] transplant and reduce the risk of complications or worsening of existing conditions.

Id. at 2. Further, ALJ Lambert held that the claims should be covered because: 1) there was a signed order for the items in the file; and 2) the CGM works with the insulin pump, which is covered. *Id*. at 3.

Thereafter, CMS appealed ALJ Lambert's decision by "referring" it to the Medicare Appeals Council. *See* Blumenfeld Declaration, Exhibit E. In particular, CMS alleged that ALJ Lambert erred by not analyzing whether the Medtronic CGM qualified as "therapeutic" under CMS 1682-R and that the Medtronic CGM did not, in fact, qualify. *Id.*

On July 23, 2019, the Council issued a decision (M-19-1748) reversing ALJ Lambert's decision and denying coverage. *See* Blumenfeld Declaration, Exhibit F. As an initial matter, the

Council stated: "Neither CMS in its Referral, nor the Council in this decision, questions the appellant's medical condition, the judgment of his doctors, or the utility of the CGM to him." *Id*. at 7. Thereafter, the Council alleged that a CGM that does not completely replace finger sticks is "precautionary" and, therefore, does not "primarily and customarily [ ] serve a medical purpose." *Id*.

As articulated by CMS, though it "does not question … the utility of the CGM" to Mr. Olsen and, presumably the need for the CGM to protect Mr. Olsen's kidney transplant, the Secretary is entitled to deference in his claim that a CGM is not "primarily and customarily used to serve a medical purpose." *Id*. at 8-9. In the Secretary's view, the three courts to decide otherwise were wrong and the Article III courts should defer to the Secretary's greater wisdom.

B. Legal Background

1. Motions for Summary Judgment

Pursuant to FED.R.CIV.P. 56(b), absent a local rule or court order otherwise, a motion for summary judgment may be filed "at any time." As indicated in the Advisory Committee Notes to both the 2009 and 2010 amendments to the FEDERAL RULES OF CIVIL PROCEDURE, "any time" includes the commencement of the case. Indeed, courts in this district have noted that in Administrative Procedure Act cases "early summary judgment motions are often appropriate." *See American Hospital Assoc. v. HHS*, 2018 WL 577397 (D.D.C. Nov. 2, 2018) (Bates, J.) (motion for summary judgment filed concurrently with Complaint appropriate, especially in APA cases). Accordingly, a motion for summary judgment filed with the Complaint is appropriate.

Moreover, an early motion for summary judgment is particularly appropriate in this case where the Secretary has already litigated, and lost, the same issue three times. Further, the very idea that a CGM is not "primarily and customarily used to serve a medial purpose" is so at odds with reality, that there is no point in delaying resolution of that matter.

2. Standard of Review

Pursuant to 42 U.S.C. § 405(g), the factual conclusions of the Secretary (if supported by substantial evidence) are conclusive.

For all other questions, the Secretary's conclusions should be evaluated using any standard available under the Administrative Procedure Act (*e.g.*, arbitrary and capricious, abuse of discretion, contrary to law, etc.). *See, e.g., Friedman v. Sebelius*, 686 F.3d 813, 826-7 (D.C. Cir. 2012) ("We therefore review the Secretary's decision to exclude the Appellants according to the arbitrary and capricious standard.").

As stated in *Motor Vehicle Mfg Assoc. of the U.S. v. State Farm Automobile Insurance Co.*, 463 U.S. 29 (1983) with regard to the standard for arbitrary and capricious:

> [T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the fact found and the choice made. In reviewing that explanation, we must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Normally, an agency rule would be arbitrary and capricious if the agency has relied on factor which Congress has not intended it consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. at 43. (internal citations and quotations omitted).

3. Statutory Construction

With regard to *statutory* construction, the first step is to employ all the traditional rules of construction. *See, e.g., SAS Inst., Inc. v. Iancu*, 138 S.Ct. 1348, 1358 (2018). Only after doing so, if the Court is unable to discern the meaning and the statute is ambiguous, should the Court consider whether *Chevron* deference should apply to any proposed construction of the statute. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency,

must give effect to the unambiguously expressed intent of Congress.").[4] Even if a statute is ambiguous, a court should only accord deference to "reasonable" constructions offered by an agency. *Id*. at 844. "Where the agency interprets a statute in a way that flatly contradicts Congress's express purpose, the court may – indeed, must – intervene and correct the agency." *See Common Cause v. Fed. Elec. Comm'n*, 692 F.Supp. 1391, 1396 (D.D.C. 1987).

4. Regulatory Construction

With regard to *regulatory* construction, again, the first step is to employ all the traditional rules of construction. *See Kisor v. Wilkie*, 139 S.Ct. 2400, 2415-6 (2019).[5] If, after doing so, the regulation is not ambiguous, then that is the end of the inquiry and the Court should give effect to the regulation. As stated in *Kisor*:

> First and foremost, a court should not give *Auer* deference unless the regulation is genuinely ambiguous. If uncertainty does not exist, then there is no plausible reason for deference. The regulation just means what it means – and the court must give it effect, as the court would any law.
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> * * *
>
> But if the law gives an answer – if there is only one reasonable construction of a regulation – then a court has no business deferring to any other reading, no matter how much an agency insists it would make more sense. Deference in that circumstance would "permit the agency, under the guise of interpreting a regulation, to create a *de facto* new regulation."

Id. (internal citations omitted). Conversely, if the regulation is still ambiguous, deference to "reasonable" constructions offered by an agency may be appropriate in certain circumstances. *Id*. at 2415-6 ("If genuine ambiguity remains, moreover, the agency's reading must still be

[4] No doubt, the Court is aware of the very substantial debate (even among members of the Supreme Court) as to the continued viability of *Chevron*.

[5] As stated in *Kisor* itself, there is very substantial debate (even among members of the Supreme Court) as to the continued viability of *Auer*.

'reasonable'."). Constructions which are arbitrary, capricious, or manifestly contrary to a statute or regulation are not reasonable. *See Chevron*, 467 U.S. at 844.

5. Durable Medical Equipment

Medicare covers "durable medical equipment." Pursuant to 42 U.S.C. § 1395x(n), "durable medical equipment" is not defined, except by examples. One specific example cited is "blood glucose monitors."

The Secretary has issued regulations further setting forth a five-part test to determine whether equipment is "durable medical equipment." *See* 42 C.F.R. § 404.202. Equipment is considered "durable medical equipment" if it:

a) Can withstand repeated use;
b) Has an expected life of at least 3 years;
c) Is primarily and customarily used to serve a medical purpose;
d) Generally is not useful to an individual in the absence of illness or injury; and
e) Is appropriate for use in the home.

6. Prior Litigation

The issue of whether a CGM qualifies as durable medical equipment has been litigated multiple times. In sum, the Secretary has refused to cover CGMs on the grounds: 1) that CGMs do not comply with the non-statutory/non-regulatory term "precautionary"; and/or 2) that CGMs do not serve a "primary medical purpose" (as opposed to the regulatory phrase "primarily … used to serve a medical purpose"). Those bases for denying CGM claims have been litigated in three district court cases.

In *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.) and *Lewis v. Azar*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.), the district courts found that the Secretary's claim that a CGM is not "primarily and customarily used to serve a medical purpose"/was "precautionary" was erroneous, not supported by substantial evidence and/or was arbitrary and

capricious, and in each case, ordered the Secretary to provide CGM coverage. Each of those decisions is final. Moreover, in each of those cases, the courts further found that the Secretary's position lacked "substantial justification" and ordered the Secretary to pay the plaintiffs' attorney fees for having to litigate the issue.

In addition, the Secretary's own Civil Remedies Division concluded that the Secretary's claim that a CGM was not covered as "precautionary" did not meet the "reasonableness standard." *See* DAB No. CR4596, 2016 WL 2851236 at *18 (reversed on other grounds).

7. Notice and Comment Requirements

Pursuant to 42 U.S.C. § 1395hh(a)(2):

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

The "paragraph (1)" referred to requires the Secretary to issue such rules, requirements or other statements of policy in the form of regulations.

Pursuant to 42 U.S.C. § 1395hh(b)/(c), proposed regulations must be published in the FEDERAL REGISTER and the public provided no less than 60 days to comment on the proposed regulations before the regulations may be published as final regulations.

In *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019), the Supreme Court held that the Medicare specific notice and comment provisions (rather than the APA' notice and comment provisions) apply to Medicare. *Id*. at 1809. Two differences between notice and comment under the Medicare Act and under the APA are: 1) the substantive/interpretive distinction under the APA does not apply to the Medicare Act; and 2) the Medicare Act requires 60 days of notice and comment rather than the 30 days under the APA. Thus, under § 1395hh, no rule, requirement, or

statement of policy that establishes or changes the standard for paying for services/benefits can take effect until the notice and comment provisions have been complied with.

8. CMS 1682-R

Without prior notice and comment, on January 12, 2017, the Secretary issued CMS Ruling 1682-R. There, the Secretary maintained that any CGM which did not completely replace finger sticks was "precautionary" and not covered. *See* Blumenfeld Declaration, Exhibit H. The Secretary asserted that if the reading from a CGM sensor had to be confirmed with a fingerstick prior to making a treatment decision, the CGM was not "primarily and customarily used to serve a medical purpose." *Id.* at 6-7.

Conversely, CGMs which do replace finger sticks the Secretary labeled "therapeutic" and considered covered. By its own terms, CMS 1682-R was effective as of the very date it issued – *i.e.*, January 12, 2017. As described in the Council's decision, this is a "coverage policy for CGM's and ancillary equipment." *See* Blumenfeld Declaration, Exhibit F at 9.

II. DISCUSSION

The Secretary's denial of Mr. Olsen's claim should be reversed (and coverage ordered) because CMS 1682-R issued in violation of law and/or because the claim that a CGM is not "primarily and customarily used to serve a medical purpose" is not supported by substantial evidence, is arbitrary and capricious, and is contrary to law. Likewise, the idea that a CGM is not a "blood glucose monitor" within the meaning of the statute is similarly flawed.

A. The Denial Based on CMS 1682-R Should be Reversed[6]

The denial of Mr. Olsen's claim should be reversed either because CMS 1682-R issued in violation of law and/or because CMS 1682-R is not supported by substantial evidence, contrary to law, and/or is arbitrary and capricious.

1. CMS 1682-R Issued In Violation of Law Denial Based on CMS 1682-R Is Unlawful

As detailed above, without prior notice and comment (including publication in the FEDERAL REGISTER), CMS 1682-R issued on January 12, 2017, effective as of that very day. That was a violation of 42 U.S.C. § 1395hh.

As stated in § 1395hh(2), "[n]o rule, requirement, or other statement of policy" that establishes or changes a standard concerning the scope of benefits, payment for services, etc. shall take effect unless promulgated by regulation issued in accordance with the notice and comment provisions. On its face, CMS 1682-R describes itself, *inter alia*, as a "statement[] of policy and interpretation." Blumenfeld Declaration, Exhibit H at 1. Further, of course, by setting forth the standard of "precautionary" and "therapeutic" CGMs, CMS 1682-R purports to establish or change the standard concerning the scope of benefits, payment for services, or eligibility of individuals receiving a CGM. Thus, under § 1395hh, CMS 1682-R cannot "take effect unless it is promulgated by the Secretary by regulation" (including compliance with the notice and comment provisions). *See* 42 U.S.C. § 1395hh.

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[6] These arguments are equally applicable to LCD L33822, which refers to Policy Article A52464, which expressly incorporates CMS 1682-R. Like CMS 1682-R, LCD L33822 and Policy Article A52464 issued on January 12, 2017, without complying with the notice and comment requirements of 42 U.S.C. § 1395hh. Likewise, LCD L33822 and Policy Article A52464 are not supported by substantial evidence/are arbitrary and capricious. In any event, while the Council's decision refers to LCD L33822 and Policy Article A52464 in the "Legal Background" section, the "Discussion" section comprising the Council's decision refers only to CMS 1682-R. Thus, the present motion focusses on the actual basis for the Council's decision – CMS 1682-R. Should the Court choose to consider LCD L33822 and Policy Article A52464, the same arguments apply.

Here, there is no genuine issue of material fact that the Secretary did not comply with the notice and comment provisions. Nothing was published in the FEDERAL REGISTER concerning proposed regulations, there was no opportunity for the public to comment, and there was no publication of final regulations. *See* 42 U.S.C. § 1395hh(b). Instead, in defiance of the statute, the Secretary simply issued a ruling establishing a new standard for benefits and, relying on that illegal standard, proceeded to reject claims (including Mr. Olsen's) on that basis. *See* Blumenfeld Declaration, Exhibit F at 10 ("We, like the ALJs, are bound by CMS Rulings.", *citing* 42 C.F.R. § 405.1063(b)).[7]

Thus, CMS 1682-R issued in violation of the law and the denial of Mr. Olsen's claim based on CMS 1682-R was also unlawful, should be reversed, and coverage ordered.

2. CMS-1682-R Not Supported By Substantial Evidence Is Arbitrary and Capricious Contrary to Law

Independent of the Secretary's defiance of the statute passed by Congress requiring notice and comment, CMS 1682-R is still an improper basis for denial of Mr. Olsen's claim because CMS 1682-R is not supported by substantial evidence, is arbitrary and capricious, and is contrary to law.

a) A Construction of "Durable Medical Equipment" That Excludes CGMs Is Erroneous

As noted above, the statute indicates that "durable medical equipment" is a covered benefit. *See* 42 U.S.C. § 1395x(n). As detailed above, even to the extent that it is determined that "durable medical equipment" is ambiguous, when the agency offers a construction that contradicts Congress' purpose, the Court must correct the agency. *Common Cause*, 692 F.Supp. at 1396.

[7] In this regard, 42 C.F.R. § 405.1063(b) indicates that CMS Rulings are "published" and further indicates that "consistent with 401.108", they are binding on "all CMS components, [and] on all HHS components that adjudicate matters under the jurisdiction of CMS[.]" As set forth in 42 C.F.R. § 401.108(a), like 42 U.S.C. § 1395hh, it is contemplated that any such Rulings will be published in the FEDERAL REGISTER. Here, again, it is undisputed that that did not occur.

Here, in CMS 1682-R, the Secretary offers a construction of the phrase "durable medical equipment" that somehow excludes the life-saving CGM that also protects Mr. Olsen's kidney transplant where it is undisputed that a CGM is "durable." Thus, whatever the phrase "durable medical equipment" means, the Secretary's construction contradicts Congress' purpose and must be rejected. *See, e.g., Mayo Found. For Med. Educ. & Research v. U.S.*, 562 U.S. 44, 53 (2011) ("manifestly contrary to the statute").

For the same reasons, the Secretary's construction is not supported by substantial evidence. There is simply no evidence that a CGM is not "durable medical equipment." A CGM cannot make waffles, wash a car, or do Westlaw searches and there is no evidence that a CGM is not durable. Indeed, CMS 1682-R assumes that the receiver portion of a CGM is, in fact, "durable" as the Secretary defines it. *See* Blumenfeld Declaration, Exhibit H at 10.

Likewise, the Secretary's construction of "durable medical equipment" as excluding a CGM is arbitrary and capricious. The Secretary's view is both counter to the evidence before the agency as to the function and qualities of a CGM and is so implausible that it cannot be ascribed to a difference in view or the product of agency expertise. *State Farm*, 463 U.S. at 43.

At the end of the day, the Secretary's proposed construction of "durable medical equipment" as excluding CGMs is not reasonable and must be rejected. *Chevron*, 467 U.S. at 844. This is especially the case where the Secretary's alleged basis for distinction between covered and non-covered CGMs (*i.e.*, "precautionary"/replacement of finger sticks) has no basis in the statute - which indicates coverage of "durable medical equipment" and is not dependent on whether finger sticks are eliminated or not.

b) A Construction of "Primarily and Customarily Used to Serve a Medical Purpose" That Excludes CGMs Is Erroneous

The Secretary has further issued regulations clarifying what is considered "durable medical equipment" including a five-part test. *See* 42 C.F.R. § 404.202. In CGM cases, including this one, the Secretary has contended that CGMs are not "primarily and customarily used to serve a medical purpose" but has not disputed that CGMs meet the other four factors.

With regard to "primarily and customarily used to serve a medical purpose", as noted in *Kisor*, the first step is to determine whether the provision is "genuinely ambiguous." *Kisor*, 139 S.Ct. at 2415-6. If the provision is not ambiguous, deferring to any proposed construction by the agency "would permit the agency, under the guise of interpreting a regulation, to create a *de facto* new regulation." *Id*.

Here, neither the Council decision nor CMS 1692-R contend that "primarily and customarily used to serve a medical purpose" is ambiguous and, indeed, it is not. As the court in *Whitcomb* noted, "The regulation defining durable medical equipment, as that term is used in the Act, is clear on its face." Whitcomb Decision at 11. Thus, because the provision is not ambiguous, "the court must give it effect[.]" *Id.* Here, again, there is simply no evidence that a CGM is *not* "primarily and customarily used to serve a medical purpose." Indeed, the Secretary's conclusion otherwise is arbitrary and capricious. That should be the end of the inquiry.

Moreover, to the extent that the Court is even willing to consider the Secretary's proposed construction of "primarily and customarily used to serve a medical purpose", that construction is unreasonable. As the courts in *Whitcomb*, *Bloom*, and *Lewis* concluded, the Secretary has never offered a construction of the phrase that makes any sense or a reason to import the non-statutory/regulatory term "precautionary" (or even a logical meaning for that term).

To the extent the Secretary attempts to recast 42 C.F.R. § 404.202 to be limited to "serve a primary medical purpose" – rather than the actual language of "primarily and customarily used to serve a medical purpose" - again, as the courts in *Whitcomb*, *Bloom*, and *Lewis* found, that proposed construction is unreasonable, and arbitrary and capricious. The Secretary's position simply flies in the face of the regulation itself and constructions which flatly contradict the regulation are unreasonable. *See, e.g., Common Cause*, 692. F,Supp. at 1396. It is to be expected that many conditions will require more than one piece of durable medical equipment to treat and there is nothing in the statute or regulation limiting coverage to a single piece of durable medical equipment that, alone entirely treats and illness or injury. Stated alternatively, there is not substantial evidence to support the Secretary's conclusion otherwise.

Even taken on its own terms, there is still not substantial evidence to support the Secretary's claim that a CGM does not serve a "primary medical purpose."[8] As the courts in *Whitcomb*, *Bloom*, and *Lewis* found, only a CGM can provide the frequency of testing and trend information necessary for diabetics (especially brittle diabetics with hypoglycemic unawareness) to manage their diabetes and avoid death.

Put simply, the idea that a CGM is not "primarily and customarily used to serve a medical purpose" is utterly baseless and at odds with reality. This is especially so in this case, where it is undisputed that one purpose of the CGM is to protect Mr. Olsen's transplanted kidney from damage. Putting aside everything else, it is non-sensical for Medicare to have paid (at least) tens of thousands of dollars for a kidney transplant, only to refuse to cover the device necessary to protect it on the grounds that a CGM serves no medical purpose. The sheer non-sensical nature of the result is one indication that the Secretary's position is without merit.

[8] Though, again, this is not what the statute says.

Moreover, the Secretary's claims regarding "precautionary", "adjunctive devices" or "the primary medical purpose" (Blumenfeld Declaration, Exhibit F at 9-10; Exhibit H at 6-7) not being "durable medical equipment"/"primarily and customarily used to serve a medical purpose" actually conflict with the Secretary's other, pre-existing regulations. For example, pursuant to National Coverage Determination (NCD) 280.1, "digital electronic pacemaker *monitors*" are covered "durable medical equipment"/are "primarily and customarily used to serve a medical purpose." *See* Blumenfeld Declaration, Exhibit G. A pacemaker *monitor* would not meet any of the Secretary's newly proposed criteria (*i.e.*, the monitor serves a precautionary function to ensure proper functioning of the pacemaker, the monitor is adjunctive to the pacemaker itself and merely complements its operation, and the monitor does not serve the "primary medical purpose" of regulating cardiac pulses). A proposed construction of a statute/regulation that conflicts with pre-existing regulations is not reasonable. *See, e.g., Gerard v. N. Transp., LLC*, 146 F.Supp.2d 63, 67 (D. Me 2006) ("When such an interpretation, however, conflicts with binding law, such as a regulation adopted after the notice and comment process established by the Administrative Procedure Act, 5 U.S.C. § 553, the Court need not give credence to the contrary interpretation.").

B. A CGM Is A "Blood Glucose Monitor" And Is "Primarily and Customarily Used to Serve a Medical Purpose"

If the Court determines that CMS 1682-R was issued in violation of law/improperly used as a basis to deny Mr. Olsen's claim, then the Court should simply reverse the Secretary's decision and order coverage without further analysis. This is so because the sole basis for CMS' Referral, and the Council's decision, was the alleged applicability of CMS 1682-R. Pursuant to 42 C.F.R. § 405.1110(c)(2), where (as here) CMS did not participate in the ALJ' hearing, then Council review is limited "to those exceptions raised by CMS." Thus, the Council review was limited to the issue of alleged applicability of CMS 1682-R. Accordingly, if the Court determines that CMS

1682-R is not applicable - either because it was illegally issued, or is not supported by substantial evidence, or is arbitrary and capricious, or for another reasons - then no further analysis is necessary or proper.

Nevertheless, even without regard to CMS 1682-R, and considering only the base issue of whether a CGM is a "blood glucose monitor" and/or "primarily and customarily used to serve a medical purpose", then the Secretary's decision should also be reversed.

1. A CGM Is a "Blood Glucose Monitor"

As noted above, pursuant to 42 U.S.C. § 1395x(n) "durable medical equipment" includes "blood glucose monitors." Thus, independent of efforts to separately construe "durable medical equipment", a CGM is a "blood glucose monitor" and is, again, covered under the statute.

There is not substantial evidence to support any claim that a CGM is not a "blood glucose monitor" within the meaning of the statute/that charge is arbitrary and capricious. Glucose in the blood is carried by "interstitial fluid" to the cells and, as noted in CMS 1682-R itself, CGMs measure the glucose that is in the interstitial fluid. *See* Blumenfeld Declaration, Exhibit H at 6. Thus, glucose levels in interstitial fluid are correlated with glucose levels in the blood itself. Accordingly, a measurement of interstitial glucose is an indirect measurement of blood glucose.

Nothing in § 1395x(n) limits "durable medical equipment" to "*direct* blood glucose monitors" and the Secretary's effort to import the word "direct" into the statute should be rejected. Indeed, traditional finger sticks/blood glucose monitors do not *directly* measure blood glucose. Instead, glucose in the blood reacts with glucose oxidase on a test strip and that reaction causes an uptake in oxygen, a color change, or an electrical signal. *See, e.g.*, "Glucose Meter" available at https://en.wikipedia.org/wiki/Glucose_meter#Continuous_glucose_monitors (accessed December 19, 2019); Blumenfeld Declaration, Exhibit H at 5." Measurement of the oxygen uptake, color

change, or electrical signal is correlated with glucose levels in the blood. Thus, even traditional finger sticks/blood glucose monitors only indirectly measure blood glucose.

Because it is undisputed that traditional finger sticks/blood glucose monitors (which indirectly measure blood glucose) fall within the meaning of "blood glucose monitor" in the statute, the Secretary's effort to exclude CGMs by importing the word "direct" simply contradicts the statute, is not supported by substantial evidence, and is arbitrary and capricious.

A CGM is a "blood glucose monitor" within the meaning of 42 U.S.C. § 1395x(n) and is a covered benefit.

2. A CGM Is "Primarily and Customarily Used to Serve a Medical Purpose"

The idea that the FDA approved, life-saving, transplant protecting device (that has no non-medical purpose) is not "primarily and customarily used to serve a medical purpose" is non-sensical on its face. For the same reasons set forth above, there is simply no evidence (much less substantial evidence) that a CGM is not "primarily and customarily used to serve a medical purpose." For years, across multiple litigations, the Secretary has failed to articulate any other use for a CGM. Indeed, even the Secretary does not "question the … utility of the CGM to [Mr. Olsen]." Thus, the only evidence is that a CGM is "primarily and customarily used to serve a medical purpose."

More generally, the Secretary's refusal to cover Mr. Olsen's CGM claim is arbitrary and capricious. In *Independent Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1246, 1260 (D.C. Cir. 1996), the court stated:

> The treatment of cases A and B, where the two cases are functionally indistinguishable, must be consistent. This is the very meaning of the arbitrary and capricious standard.

As noted above, coverage of the functionally indistinguishable CGMs (indeed, the same CGM) was approved/ordered in the *Whitcomb*, *Bloom*, and *Lewis*' cases. Thus, the Secretary's effort to treat Mr. Olsen's case differently is, by definition, arbitrary and capricious.

C. Coverage Should Be Ordered

Pursuant to 42 U.S.C. § 405(g) (fourth sentence):[9]

> The court shall have the power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing.

As detailed above, because CMS' Referral and the Council's decision were limited to and premised on the alleged application of CMS 1682-R, there is no other proper basis for denying Mr. Olsen's claim. Thus, if the Court concludes that the Council was in error in this regard, then there is nothing further to be done by the Council and the Court should just issue an Order requiring coverage and remand to the Council to effectuate the Court's decision.

III. CONCLUSION

For the reasons set forth above, the Court should hold that CMS 1682-R is invalid, reverse the Secretary's denial of Mr. Olsen's claim, and order the Secretary to cover Mr. Olsen's claim.

Alternatively, the Court should simply hold that a CGM is "durable medical equipment"/"primarily and customarily used to serve a medical purpose", reverse the Secretary's denial of Mr. Olsen's claim, and order the Secretary to cover Mr. Olsen's claim.

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Respectfully submitted,

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[9] As modified by 42 U.S.C. § 1395ff(b)(1)(A).

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